

Docket No: 10139/04602 (00616-05PUS1)

REMARKS

Claims 1 - 18 are pending in the present application. In view of the following remarks, it is respectfully submitted that all of the pending claims are allowable.

Claims 1, 2, 7, 9, 13, 14 and 17 stand rejected under 35 U.S.C. § 103(a) 102(b) as anticipated by U.S. Patent No. 5,626,613 to Schmieding (hereinafter "Schmieding"). The Examiner states that Schmieding discloses a device having a longitudinal shape with a central axis, a first end, and a second end, wherein the device is helical. (See 2/4/08 Office Action, pp. 2 - 3). The Examiner further asserts that the device of Schmieding is capable of being used as an intramedullary nail in the bone of an organism smaller than a human. (See 4/4/07 Office Action, p. 5). In the Advisory Action dated June 13, 2007, the Examiner also states that the term "intramedullary" is a functional, not structural, adjective and that, therefore, Schmieding reads on the structural limitations of claim 1. (See 6/13/07 Advisory Action, p. 3).

Claim 1 recites an osteosynthetic device comprising "*an intramedullary nail* having a longitudinal shape with a central axis, a first end, and a second end, wherein the shape of the device is helical." (Emphasis added).

Initially, it is respectfully submitted that the term "intramedullary nail" is clearly recognized by those skilled in the art as defining a specific device having defined structural qualities -- i.e., the nail must be sized and shaped to conform to the medullary canal into which it will be inserted, the materials must be biocompatible and strong enough to absorb the stresses to which the bone will be exposed, etc. The specification of the present application uses this term "intramedullary nail" completely consistently with this meaning of the term as it is understood by those skilled in the art. (See Specification, ¶ [0002], [0003], [0007], [0012], [0015], [0031]). A nail is not an intramedullary nail simply because it can fit in the medullary canal. Although a penny nail or horseshoe nail could fit in the medullary canal, this does not make such a nail an intramedullary nail as neither of these nails has the structure necessary to perform the function of an intramedullary nail. Although the term intramedullary nail does indicate the intended use of the item, it also defines its structure in the same manner as does the term "horseshoe nail." It is respectfully submitted that the Examiner's assertion that this term is solely an indication of intended use ignores the realities of this technology and the way in which this term is understood

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by those skilled in the art.

Furthermore, even without the structural implications of the recitation of an "intramedullary" nail, Schmieding still fails to show a "nail." Specifically, Schmieding shows a corkscrew suture anchor which is in no way a nail. (See Schmieding, Abstract).

It is further submitted that the Examiner's assertion that the Schmieding suture anchor "is capable of being used as an intramedullary nail if one so desired" is unfounded. (See 6/13/07 Advisory Action, p. 2). There is nothing in the Schmieding reference that makes such a claim and in fact, this structure is entirely unsuitable for this purpose. Thus, it is respectfully submitted that this assertion is based wholly on speculation by the Examiner, a misunderstanding of the meaning of the term "intramedullary nail" and a failure to consider or understand the function of the structure as indicated in this application and as understood generally by those skilled in the art. Specifically, there is absolutely nothing in the Schmieding reference that indicates that the suture anchor 2 may be inserted into the medullary canal. Consequently, there is no indication in this reference that a suture anchor 2 so inserted into the medullary canal could serve as an intramedullary nail or how it could be so used.

It is therefore respectfully submitted that the Examiner has not made a *prima facie* case of anticipation of independent claim 1, and that the rejection of claim 1, along with the rejections of dependent claims 2, 7, 9, 13, 14, and 17, should be withdrawn.

Claims 8, 10 and 12 stand rejected under 35 U.S.C. § 103(a) as obvious over Schmieding.

Claim 1 has been recited above and discussed with reference to the 35 U.S.C. § 102(b) rejection. Claims 8, 10 and 12 depend from and therefore include all the limitations of independent claim 1. As discussed above, Schmieding does not teach or suggest the limitations of independent claim 1 and claim 1 is allowable over Schmieding. Accordingly, because claims 8, 10 and 12 depend from and, therefore, include all of the limitations of independent claim 1, it is respectfully submitted that these claims are also allowable.

Furthermore, it is submitted that the fact that Schmieding's device is a suture anchor and with no indication that it may be used as an intramedullary nail. The Examiner's assertion that

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the claimed shapes which enhance the functioning of an intramedullary nail would be a mere design choice ignores the impact such a shape change might have on the actual function of the suture anchors 2 of Schmieding. This speculation by the Examiner is entirely unsupported by the cited reference and it is submitted that the suggested changes are likely to impede the functioning of the suture anchors 2. At the least, it is submitted that nothing in Schmieding suggests the changes proposed by the Examiner or that any such modifications would make the Schmieding device more suited for its purpose and, therefore, that this reference provides absolutely no motivation for the proposed modification which constitutes an improper hindsight reconstruction of the invention.

Claims 3 - 6, 11 and 15 - 16 stand rejected under 35 U.S.C. § 103(a) as obvious over Schmieding.

Claim 1 has been recited above and discussed with reference to the 35 U.S.C. § 102(b) rejection. Claims 3 - 6, 11 and 15 - 16 depend from and therefore include all the limitations of independent claim 1. As discussed above, Schmieding does not teach or suggest the limitations of independent claim 1 and claim 1 is therefore allowable. Accordingly, because claims 3 - 6, 11 and 15 - 16 depend from and, therefore, include all of the limitations of independent claim 1, it is respectfully submitted that these claims are also allowable.

Claim 18 stands rejected under 35 U.S.C. § 103(a) as obvious over Schmieding.

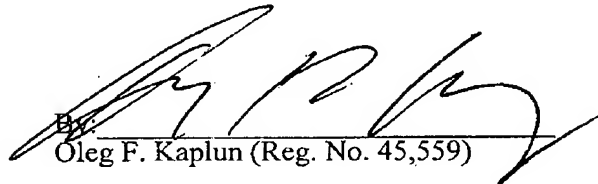
Claim 1 has been recited above and discussed with reference to the 35 U.S.C. § 102(b) rejection. Claim 18 depends from and therefore includes all the limitations of independent claim 1. As discussed above, Schmieding does not teach or suggest the limitations of independent claim 1 and claim 1 is therefore allowable over Schmieding. Accordingly, it is respectfully submitted that this claim is allowable for the same reasons stated in regard to claim 1.

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It is therefore respectfully submitted that all of the presently pending claims are allowable. All issues raised by the Examiner having been addressed, an early and favorable action on the merits is earnestly solicited.

Respectfully submitted,

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